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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,724	11/07/2001	Michael N. Gould	960296.97711	7402

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EXAMINER
JONES, DAMERON

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/014,724	Applicant(s) GOULD ET AL.	
	Examiner D. L. Jones	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 17-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 17-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8&9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 3, filed 2/12/02, wherein claims 10-16 were canceled.

Note: Claims 1-9 and 17-33 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to methods of sensitizing tumor cells comprising using monoterpene or sesquiterpenes.

STATUTORY DOUBLE PATENTING

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1-9 and 17-25 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-15 of copending Application No. 09/878,797. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

102 REJECTIONS

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 26-29, 32, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Gould et al (US Patent No. 5,587,402).

Gould et al disclose the regression of mammalian leukemia cell tumors wherein perillyl alcohol is administered to a subject (see entire document, especially, abstract). In addition, Gould et al disclose (1) that it is possible to test the measurement of protein isoprenylation by incubating extracts with a radioactive isoprene and visualizing the protein by fluorography (columns 2-3, bridging paragraph). (2) Various monoterpenes such as limonene, perillyl alcohol, sobrerol, myrcene, pinene, cavone, terpineol, and uroterpenol (see column 4, Table 1) were analyzed for their ability to inhibit isoprenylation in mouse embryo cells. (3) Various concentrations of perillyl alcohol was used and shown to inhibit growth of a number of human cancer cell lines (column 5,

lines 8-13). (4) The effects of dietary perillyl alcohol on tumor regression and inhibition in rats were studied (columns 5-6, lines 14-68 and 1-68, respectively). (5) In column 7, lines 35-68, in vivo experiments are conducted using perillyl alcohol in patients with leukemia. (6) In column 8, lines 33-58, experiments were conducted with perillyl alcohol and limonene. Later, IL-3 was added.

Thus, both Applicant and the cited prior art disclose a method of sensitizing tumor cells to immunomodulatory agents wherein a monoterpene, perillyl alcohol, is administered.

7. Claims 1-9 and 17-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al (Eicosanoids and Other Bioactive Lipids in Cancer, Inflammation, and Radiation Injury 2, 1997, pp. 825-830).

Miller et al disclose tumor radiosensitization (see entire document). In addition, Miller et al disclose (1) lovastatin concentrations which exhibit moderate toxicity yield a significant decrease in radioresistance (page 825, second paragraph). (2) Monoterpenes (e.g., limonene) inhibit protein isoprenylation under non-toxic conditions and exhibit chemotherapeutic activity against chemically induced carcinomas (page 8,26, first incomplete paragraph). (3) The cellular response to radiation was determined using limonene (pages 826-827, bridging paragraph; page 827, second complete paragraph). (4) Exposure to limonene resulted in significant increase in radiation sensitivity of prostate, lung, colon, and breast tumors (page 827, second complete paragraph; page 828, Table 1). (5) It is also noted that some of the experiments

conducted by Miller et al involved the use of gliboblastoma cells (page 827, second complete paragraph; page 828, second complete paragraph).

Thus, both Applicant and Miller et al disclose a method of sensitizing tumor cells to radiation wherein a monoterpene is utilized.

8. Claims 1-9, 17, 18, 20-26, and 28-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers et al (WO 94/20080).

Myers et al disclose the use of monoterpenes and sesquiterpenes in the treatment of cancer. The treatment involves administering an effective amount6 of a selected terpene to a mammal having prostate cancer, colon cancer, astrocytoma, or sarcoma. Possible terpenes include cyclic monoterpenes (e.g., limonene), non-cyclic monoterpenes (e.g., myrcene and citral), and non-cyclic sesquiterpenes (e.g., farnesol, farnesal, farnesylic acid, and nerolidol). In addition a method of sensitizing a cancer to radiation is disclosed that involves administering an effective amount of the terpene to a mammal. Also, Myers et al disclose a method of inhibiting the growth of cancer cells wherein a terpene comes in contact with prostate, colon, osteosarcoma, or glioblastoma cells (see entire document, especially, abstract; pages 2-3, bridging paragraph; pages 6-7, bridging paragraph; pages 8-9. Compounds 1-11; page 16, 'Sensitizing a Cancer to Radiation'; pages 19-20, Table 1; Pages 20-21, Example 2; pages 21-22, Example 3; pages 22-23, Example 5; and page 25, claim 1).

Thus, both Applicant and Myers et al disclose a method of sensitizing tumor cells to radiation wherein monoterpenes or sesquiterpenes are utilized.

103 REJECTIONS

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-5, 17-21, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al (WO 94/20080) in view of Gould et al (US Patent No. 5,587,402).

Myers et al (see discussion above) fail to disclose the use of perillyl alcohol in its methods of sensitizing tumor cells to radiation.

Gould et al (see discussion above).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Myers et al using the teachings of Gould et al and generate a method of sensitizing tumor cells to radiation using the monoterpene, perillyl alcohol, because one would be motivated to replace one monoterpene with another monoterpene known to be useful for tumor analysis since both documents disclose the use of monoterpenes with tumor cells.

11. Claims 1-5, 17-21, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al (Eicosanoids and Other Bioactive Lipids in Cancer,

Inflammation, and Radiation Injury 2, 1997, pp. 825-830) in view of Gould et al (US Patent No. 5,587,402).

Miller et al (see discussion above) fail to disclose the use of perillyl alcohol in its methods of sensitizing tumor cells to radiation.

Gould et al (see discussion above).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Miller et al using the teachings of Gould et al and generate a method of sensitizing tumor cells to radiation using the monoterpene, perillyl alcohol, because one would be motivated to replace one monoterpene with another monoterpene known to be useful for tumor analysis since both documents disclose the use of monoterpenes with tumor cells.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Jones
Primary Examiner
Art Unit 1616

February 5, 2003